GDPR, Common Law, Consent

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Where are researchers struggling

&

how could the patient voice help?

Adam Glaser
University of Leeds, UK

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Role
Professor of Paediatric Oncology & Late Effects

Consultant Paediatric Oncologist & Late Effects Physician

Research
Cancer Survivor Intelligence Group

Late effects of cancer

£5 million grants

Clinical
Long term follow-up service
1,500 survivors age 6-56 years

Acute Paediatric and Adolescent Oncologist
100 new cases 0-18 y per annum
100 new cases 18-24 y per annum

The Leeds Teaching Hospitals NHS Trust

2nd largest hospital group in England

Session

- Scene Setting
- How is this affecting research?
- How could the patient voice help?
- GDPR
- Data Protection Act 2018
- Common Law
  - Duty of Confidentiality
- Consent

Scene Setting

The General Data Protection Regulation (GDPR)

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Sets the minimum standards for data processing across all 28 EU countries

Strict new rules on controlling and processing personally identifiable information

Extends the protection of personal data and data protection rights by giving control back to EU residents

Forms part of the data protection regime in the UK, together with the new *Data Protection Act 2018* (DPA 2018)

Replaced the *1995 EU Data Protection Directive* on May 25, 2018

Official Purpose of GDPR?

GDPR will significantly strengthen a number of rights: individuals have more power to demand companies reveal or delete the personal data they hold

Regulators will be able to work in concert across the EU for the first time, rather than having to launch separate actions in each jurisdiction; and their enforcement actions will have real teeth, with the maximum fine now reaching the higher of €20m (£17.5m) or 4% of the company's global turnover

Alex Hern The Guardian 21 May 2018

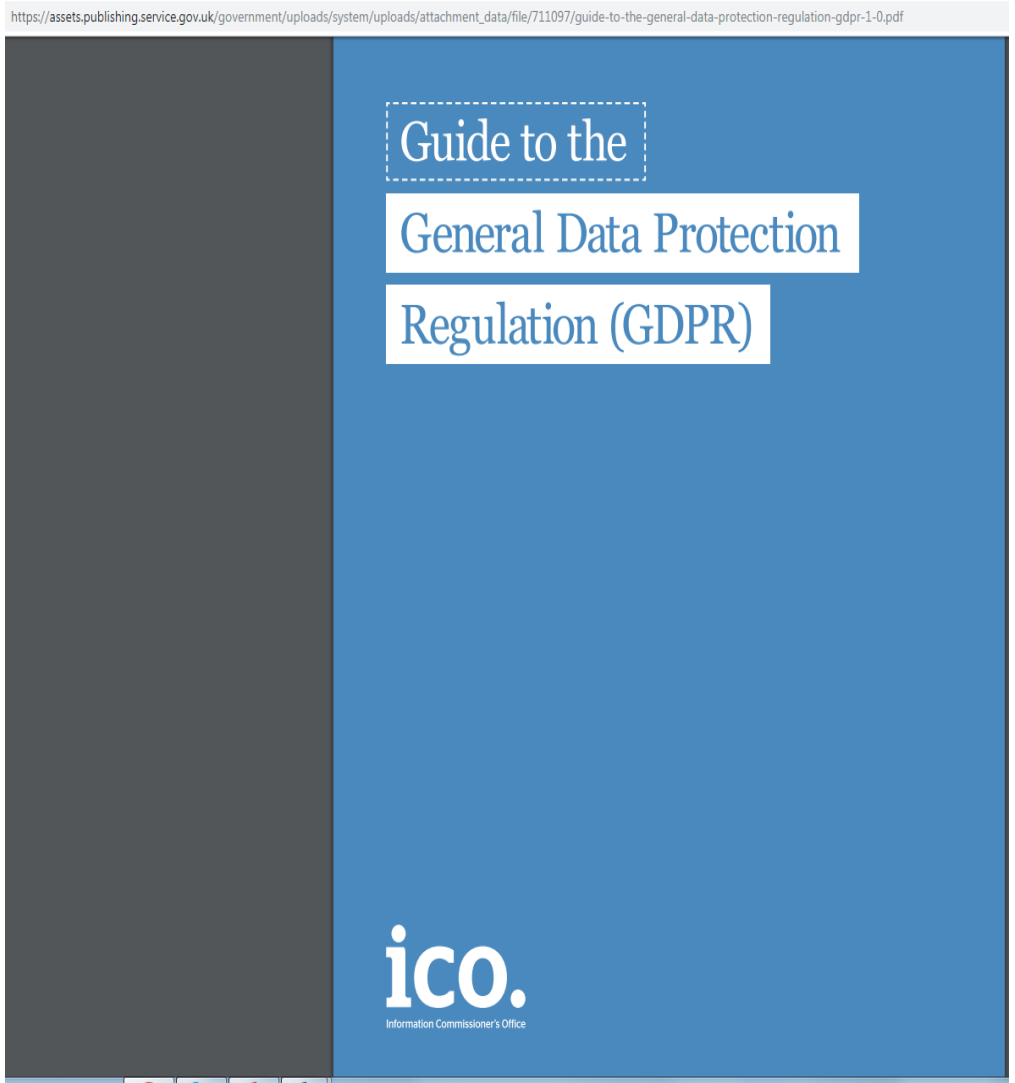
https://www.theguardian.com/technology/2018/may/21/what-is-gdpr-and-how-will-it-affect-you

Turn to the experts for clear interpretation

Information Commissioner's Office

201 pages

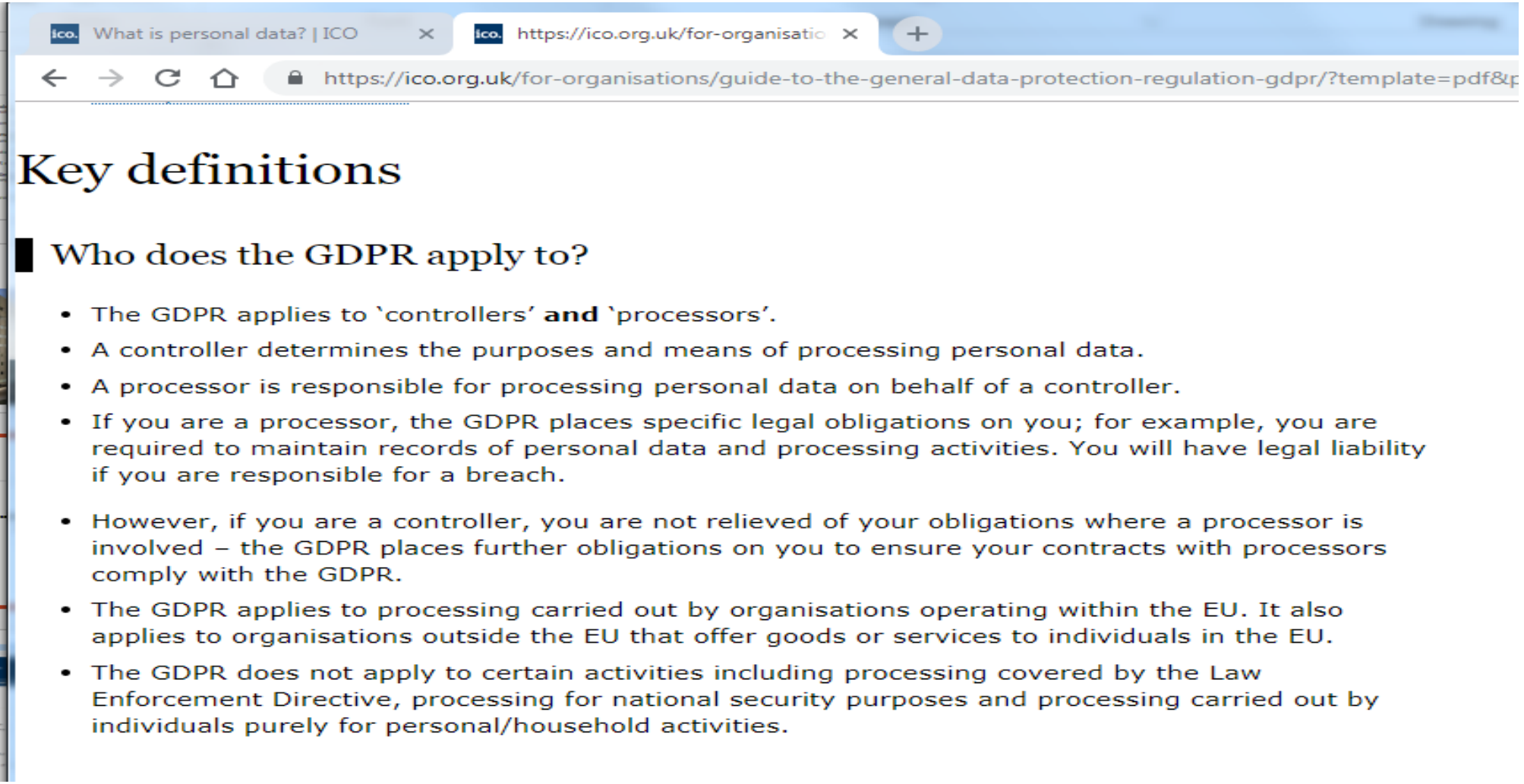
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/711097/guide-to-the-general-data-protection-regulation-gdpr-1-0.pdf



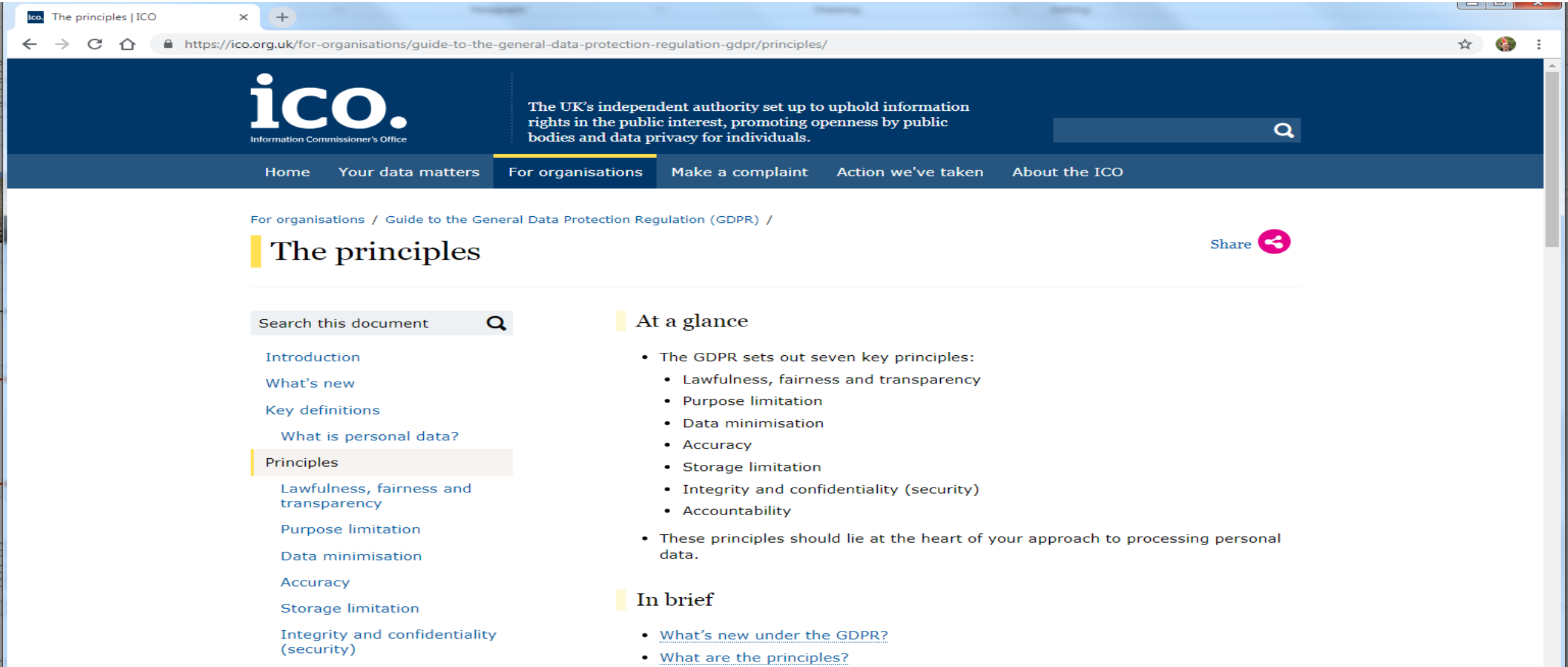
What is GDPR?

ICO 2018

https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/?template=pdf&patch=97#link0



GDPR 7 Key principles



What is personal data?

At a glance

- Understanding whether you are processing personal data is critical to understanding whether the GDPR applies to your activities.
- Personal data is information that relates to an identified or identifiable individual.
- What identifies an individual could be as simple as a name or a number or could include other identifiers such as an IP address or a cookie identifier, or other factors.
- If it is possible to identify an individual directly from the information you are processing, then that information may be personal data.
- If you cannot directly identify an individual from that information, then you need to consider whether the individual is still identifiable. You should take into account the information you are processing together with all the means reasonably likely to be used by either you or any other person to identify that individual.
- Even if an individual is identified or identifiable, directly or indirectly, from the data you are processing, it is not personal data unless it 'relates to' the individual.
- When considering whether information 'relates to' an individual, you need to take into account a range of factors, including the content of the information, the purpose or purposes for which you are processing it and the likely impact or effect of that processing on the individual.
- It is possible that the same information is personal data for one controller's purposes but is not personal data for the purposes of another controller.
- Information which has had identifiers removed or replaced in order to

Scene Setting

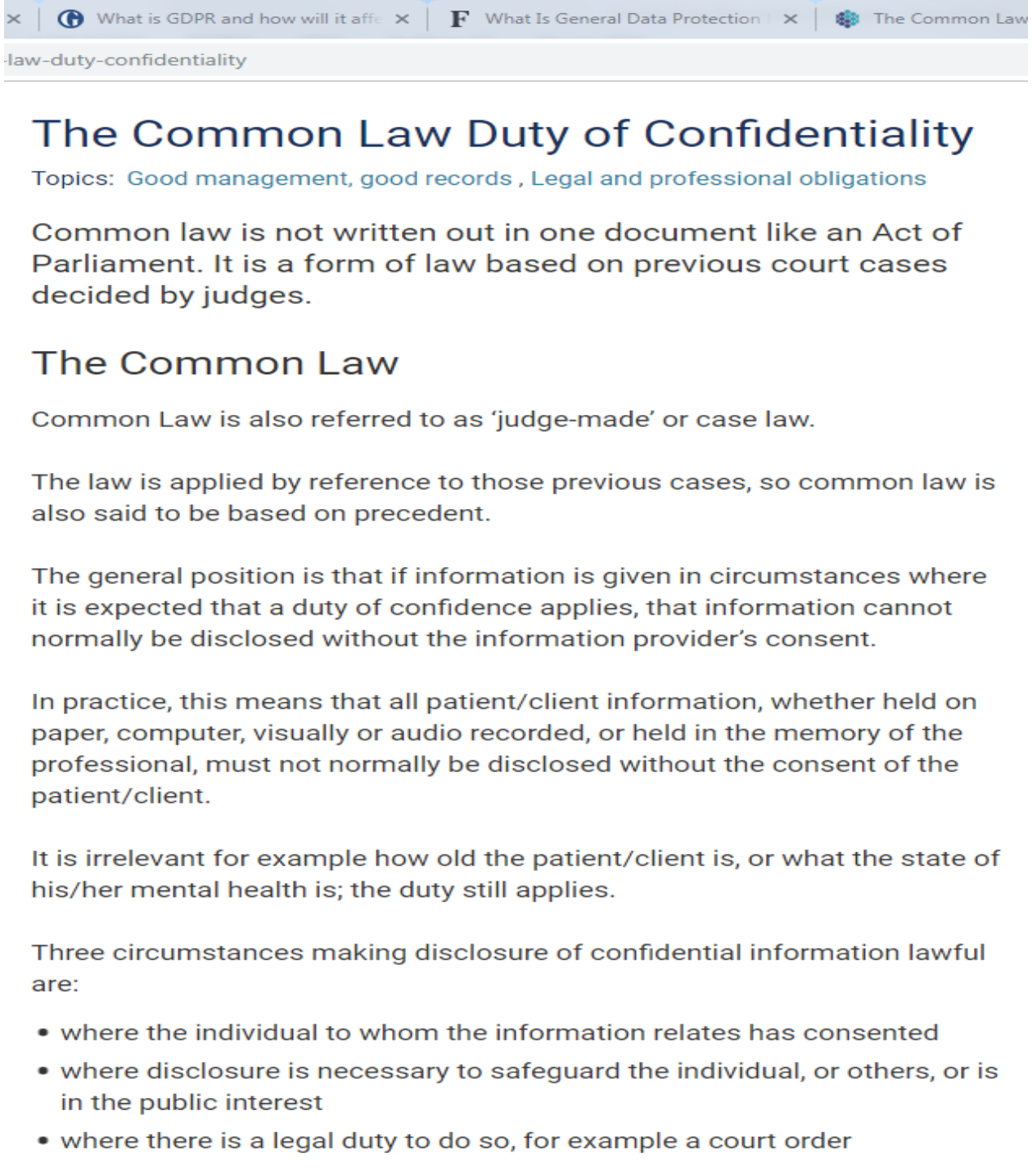
Data Protection Act 2018

https://www.gov.uk/government/collections/data-protection-act-2018

Scene Setting

Common Law

https://www.health-ni.gov.uk/articles/common-law-duty-confidentiality



What is GDPR and how will it affe | What Is General Data Protection | The Common Law

-law-duty-confidentiality

The Common Law Duty of Confidentiality

Topics: Good management, good records , Legal and professional obligations

Common law is not written out in one document like an Act of Parliament. It is a form of law based on previous court cases decided by judges.

The Common Law

Common Law is also referred to as 'judge-made' or case law.

The law is applied by reference to those previous cases, so common law is also said to be based on precedent.

The general position is that if information is given in circumstances where it is expected that a duty of confidence applies, that information cannot normally be disclosed without the information provider's consent.

In practice, this means that all patient/client information, whether held on paper, computer, visually or audio recorded, or held in the memory of the professional, must not normally be disclosed without the consent of the patient/client.

It is irrelevant for example how old the patient/client is, or what the state of his/her mental health is; the duty still applies.

Three circumstances making disclosure of confidential information lawful are:

- where the individual to whom the information relates has consented
- where disclosure is necessary to safeguard the individual, or others, or is in the public interest
- where there is a legal duty to do so, for example a court order

So good so far

- Legislation clear and in our interests
- Protects us from Big Brother

BUT…….

How is this affecting research?

- Multiple statutory bodies implementing the legislation within the research arena utilising big data

  duplication

- Suggestion of varying, changing and at times inconsistent interpretation of GDPR and DPA 2018?

Bodies involved

- Health Research Authority
    1. Research Ethics Committee
    2. Confidentiality Advisory Group

- NHS Digital *safe-haven*
    - IGARD

- Public Health England
    - Office for Data Release

Independent Group Advising on the Release of Data IGARD

- Considers all requests for dissemination of confidential information, as defined in section 263 of the *Health and Social Care Act*, through the Data Access Request Service (DARS)

- Aims to improve transparency, accountability, quality and consistency through robust scrutiny of NHS Digital distributions

- IGARD independently assesses applications for data to NHS Digital to minimise risks of any information disclosure

https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data

Office for Data Release PHE

PHE makes its data available to *bona fide* individuals and organisations who wish to use it for acceptable health and care purposes, providing patient confidentiality is not compromised and appropriate research ethics approvals have been granted

https://www.gov.uk/government/publications/accessing-public-health-england-data/arrangements-for-access-to-national-disease-registration-data-held-by-phe

Still all feels very good in principle BUT in practice…

Getting approval for research involving patient data

- Cumbersome process
- Duplication of reviews to ensure compliance with legislation
- Consent forms and Participation Information Sheets become
  - Complex
  - Lengthy
  - Un-interpretable

Study to explore the benefits of PPI in a research programme

On line questionnaire for PPI participants in a 4 year multi-centre programme

8 Screens of information before the survey of under 10 screens of questions.

The LAPCD study presented a novel model of patient and public involvement through development of a separate work-stream to help ensure that the User Advisory Group (UAG) was involved throughout the study. The aim of this evaluation is to explore how well this model of patient and public involvement worked for the study, what impacts it had on the study, and to report any challenges encountered.

Why have I been chosen?
You have been chosen because you are a member of the LAPCD team and have experience of patient and public involvement in your individual work package in the LAPCD study or through the LAPCD study as a whole (e.g. advisory group meetings).

What do we want the research to find out?
The aim of the research is to explore the impacts of patient and public involvement on the LAPCD research study, and to explore any the challenges experienced. This would include exploring what processes and contexts worked well to develop effective patient and public involvement throughout the study, and what hindered the process.

Why are we doing this study?
There has been a rapid growth in patient and public involvement in healthcare research in the past ten years. However, although the UK Government is committed to PPI in health research, there is a need for more robust evidence of its benefits, and a need to explore what works, for whom, why, and in what context. The current evidence base lacks satisfactory reporting of PPI in published papers, and there is a need for more evaluation studies of PPI.

What would I have to do?
If you agree to participate, we will ask you to complete a short online survey which asks you to give examples of your experience of PPI in the LAPCD study, ask you about factors you think supported the PPI in the LAPCD study, and factors which hindered the PPI in the LAPCD study and ask if you experienced personal benefits from PPI in the LAPCD. We will also ask you to tell us about examples of PPI in the LAPCD study that you have been involved in, and ask you what modifications to the method of involving service users in the LAPCD study would have improved PPI. This survey will take about 20 minutes to complete. You will be asked to give your consent to participate at the start of the questionnaire. However, if you change your mind and don't want your responses used for the purposes of this study you can withdraw your responses at any time up to the end of data collection and your data will not be used in reporting on this study. While every effort will be made to keep responses confidential, please be aware that those within the wider research team may be able to identify you from your responses. If you are providing examples of working within specific work packages then it may become evident who you are to other members of the research team. Your responses will be confidential and anonymous in external reports and published papers. We hope you will feel comfortable in responding to all the items in the survey but if you would rather not complete some questions you can simply leave them blank and move on to the next one.

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After you have completed the online survey we will ask you to take part in a short telephone interview or face to face interview to explore your experiences of PPI in the LAPCD study further. We will contact you to arrange a convenient time to phone you or meet up with you. Consent for these interviews will be recorded over the phone or by completing a consent form immediately prior to the interview. With your permission, we will digitally record the interviews.

Do I have to take part?
No. It is up to you to decide whether or not to take part. Participation, non-participation or withdrawal will not impact on your employment as part of the LAPCD team or your statutory rights either now or in the future. Please let the research team know if you would like to participate.

What will happen to the information I give?
The information collected in this study will be analysed by the research team and the results will be published in a peer-reviewed journal. We will write the paper using the EQUATOR GRIPP reporting guidelines for patient and public involvement, to help build a stronger evidence base for patient and public involvement. This will make it easier in the future to draw together our collective understanding of what works, for whom, why, and in what context. By publishing the results of the study other research teams can learn from our experience. A summary of the results of the study can be obtained by emailing Jo Brett (jbrett@brookes.ac.uk).

What do we want to do with the results of this work?
We will use the results to write a paper about our experiences of patient and public involvement which will be published in a peer reviewed journal. We can also use the results to help us conduct patient and public involvement in future research studies.

What are the disadvantages of taking part?
We do not foresee any disadvantages to your taking part in the study. It will not affect your current or future employment in any way. If you have any concerns, please do not hesitate to contact your line manager or the principal investigator of the LAPCD study, Adam Glaser (A.Glaser@leeds.ac.uk or a.glaser@nhs.net).

What are the benefits of taking part?
The study may help you reflect on the patient and public involvement in the LAPCD study. These may be positive reflections or may be reflections of how PPI could be done

study, Adam Glaser (A.T.Glaser@lboro.ac.uk or a.glaser@nhs.net).

What are the benefits of taking part?
The study may help you reflect on the patient and public involvement in the LAPCD study. These may be positive reflections or may be reflections of how PPI could be done differently. Many people find being involved in research a positive experience.

Will my taking part in the study be kept confidential?
Yes, all the information you give will remain anonymous. The survey software will not store any information linked to a specific person or device (e.g. an IP address). You will not be asked to provide your name, the name of your organisation or any other identification. Only the researchers will have access to the data, which will be stored in accordance with the University's policy on Academic Integrity. This means that all data will be securely stored in paper or electronic form for a period of 10 years when the project is finished. The same process will be applied to the interview transcripts. If you require further information please contact the University's Information Management Team on 01865 485420 or email info.sec@brookes.ac.uk.

As stated above, please be aware that those within the research team may be able to identify you from your responses in the final internal report. However in external reports or published papers your data will be anonymous.

The information you provide will be stored securely by Oxford Brookes University for 10 years from completion of the study, for audit purposes only. Oxford Brookes University will destroy it after this date.

How will my data be protected?
Oxford Brookes University is the sponsor for this study and will act as the data controller for the study. This means that we are responsible for looking after your information and using it properly. Personal identifiable data will be kept separately from the survey and interview data. All data will be kept on password protected computer and/or in a locked cabinet. The research data will only be accessed by the research team for the purposes of this study or by Oxford Brookes staff for monitoring and auditing purposes.
Your rights to access, change or move your information are limited after the end of the study, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use protect your information at:
https://www.brookes.ac.uk/it/information-management

What if I change my mind?
If you wish to withdraw from the study and have any personal information that identifies you deleted, you may do so by contacting the Jo Brett on 01865 482696 or JBrett@Brookes.ac.uk. You do not need to give a reason why you want to withdraw. Your withdrawal will not affect your employment rights or your statutory rights either now or in the future. No further information will be sought and we will not contact you again.

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Who has reviewed the study?
The study has been reviewed and approved by the Oxford Brookes University Research Ethics Committee (UREC E18020).

Who is funding and organising this study?
This study is funded by Prostate Cancer UK (PCUK) and the Movember Foundation. Dr Adam Glaser from the University of Leeds and Dr Anna Gavin from Queen's University Belfast are the Chief Investigators of the LAPCD study. The other organisations involved in the wider study are Oxford Brookes University, University of Southampton and Public Health England. This evaluation study of PPI in the LAPCD study is organised by Oxford Brookes University in collaboration with the LAPCD User Advisory Group.

What if there is a problem?
If you have a concern or questions about any aspect of this study, contact Jo Brett Tel: 01865 482696 or email: jbrett@brookes.ac.uk

Alternatively, if you wish to make a complaint, you may prefer to contact the Oxford Brookes University Ethics committee:

Dr. Sarah Quinton
Chair of the University Research Ethics Committee
Ethics@Brookes.ac.uk
Oxford Brookes University, Gypsy Lane, Headington, Oxford OX3 0BE

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Survey Completion
0% 100%

Privacy notice for research participants

This privacy notice provides information on how Oxford Brookes University collects and uses your personal information when you take part in one of our research projects. Please refer to the research participant information sheet for further details about the study and what information will be collected about you and how it will be used.

Oxford Brookes University (OBU) will usually be the Data Controller of any data that you supply for this research. This means that we are responsible for looking after your information and using it properly. The exception to this is joint research projects where you would be informed on the participant information sheet as to the other partner institution or institutions. This means that they will make the decisions on how your data is used and for what reasons. You can contact the University's Information Management Team on 01865 485420 or email info.sec@brookes.ac.uk.

Why do we need your data?

The LAPCD study presented a novel model of patient and public involvement through development of a separate work-stream to help ensure that the User Advisory Group (UAG) was involved throughout the study. The aim of this evaluation is to explore how well this model of patient and public involvement worked for the study, what impacts it had on the study, and to report any challenges encountered. The results of this evaluation will inform better practice around PPI in future studies.

OBU's legal aspect for collecting this data: You are consenting to providing it to us.

What type of data will Oxford Brookes University use?

The type of data collected in this study is survey data and qualitative interview data.

Who will OBU share your data with?

During the analysis of this study, OBU may share anonymised data with UAG members on the study (Hugh Butcher, John Keenan and Daryl Catton) from the LAPCD User Advisory Group and with Eila Watson (OBU) and Penny Wright (University of Leeds), who are co-applicants on the wider LAPCD study.

Will OBU transfer my data outside of the UK? No.

What rights do I have regarding my data that OBU holds?

- You have the right to be informed about what data will be collected and how this will be used
- You have the right of access to your data
- You have the right to correct data if it is wrong
- You have the right to ask for your data to be deleted
- You have the right to restrict use of the data we hold about you

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- You have the right of access to your data
- You have the right to correct data if it is wrong
- You have the right to ask for your data to be deleted
- You have the right to restrict use of the data we hold about you
- You have the right to data portability
- You have the right to object to the university using your data
- You have rights in relation to using your data in automated decision making and profiling.

Where did OBU source my data from?
Your details have been received from the Life after prostate cancer diagnosis team, because you are either currently working on the LAPCD study or you have previously worked on the LAPCD.

Are there any consequences of not providing the requested data?
There are no consequences of not providing data for this research. It is purely voluntary.

Will there be any automated decision making using my data?
There will be no use of automated decision making in scope of UK Data Protection and Privacy legislation.

How long will OBU keep your data?
In line with Oxford Brookes policies data generated in the course of research must be kept securely in paper or electronic form for a period of time in accordance with the research funder or University policy. The data from this study will be kept for 10 years.

Who can I contact if I have concerns?
In the event of any questions about the research study, please contact the researchers in the first instance (contact details in the study participant information sheet). If you have any concerns about the way in which the study has been conducted, contact the Chair of the University Research Ethics Committee at ethics@brookes.ac.uk. For further details about information security contact the Information Management team on info.sec@brookes.ac.uk

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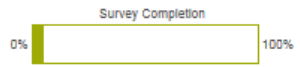

OXFORD BROOKES UNIVERSITY

For the purposes of carrying out this Survey, the University uses the survey tools provided by Qualtrics with whom the University's Faculty of Health and Life Sciences holds an agreement. There is always a certain element of risk of data loss when data is collected and processed in an internet environment. This risk cannot be eliminated entirely and participants consenting to take part in the survey need to be aware of this risk. However, personal data will be minimised to the extent possible for the survey and the University believes that Qualtrics offers sufficient guarantees to keep the data secure while it is being processed. These security obligations are set out in the agreement between Qualtrics and the University.

Further information about Qualtrics can be found on the following web site: http://qualtrics.com/

☐ I have read the patient information, the privacy notice for research participants, and I consent to participate in this survey

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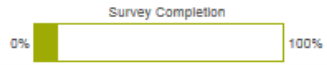

How can the patient voice help?

- Is there a genuine problem?
- Solution?

Is there a problem?

- Valuable legislation with essential principles is having unintended unwanted consequences
- Restricting progress and valuable research that the public are keen for
- Waste of the public purse
  - Public bodies duplicating activity
  - Delaying charity, NIHR and research council funded research

Solution

Stop duplication of activities by public organisations in providing approvals for data sharing

HRA/NHS Digital/PHE

Clear guidance to support consistent and reproducible recommendations